

claims 3 and 8 under 35 U.S.C. 103(a) as being unpatentable over Nasir, in view of Dixon, and in further view of McMahon et al., U.S. Patent No. 5,166,078 ("McMahon").

For the reasons set forth below, Applicants traverse the claim rejections and request reconsideration.

## **I. Claim Rejections**

With respect to the Examiner's rejections of the claims under § 103, Applicants submit that the Examiner has not established a *prima facie* case of obviousness. In particular, a *prima facie* case of obviousness requires the following three elements: (1) a prior art suggestion or motivation to modify the reference or to combine reference teachings; (2) a prior art teaching that the asserted modification or combination would have a reasonable expectation of success; and (3) the prior art reference or references must teach or suggest all the claim limitations. *See* MPEP § 2143. However, the Examiner has not established any of these three elements.

With respect to element (1), the requirement of a prior art suggestion or motivation to combine references, the Examiner's position is that the Nasir reference "teaches a homogeneous assay using fluorescence polarization to analyze mycotoxins in grains." In fact, the Nasir reference does not teach fluorescence polarization assays of mycotoxins generally, but rather that fluorescence polarization has *potential* in this area:

FP [fluorescence polarization], with its latest developments in simple and relatively inexpensive instrumentation, is a technique of great potential in this area of research.

*See* Nasir, p. 182. Moreover, as the Examiner has conceded, the Nasir reference does not refer to deoxynivalenol (DON) or other trichothecenes specifically.

Although the Pestka reference teaches the desirability of testing for mycotoxins, including DON and other trichothecenes, Pestka does not mention the fluorescence polarization technique at all. To the contrary, Pestka teaches using RIA and ELISA techniques to detect DON and other trichothecenes. Indeed, Pestka discloses that ELISA immunoassay kits for DON and other trichothecenes are commercially available and that DON ELISAs have been certified by the Federal Grain Inspection Service. *See* Pestka, pp. 126-127.

Accordingly, the Examiner has not identified a proper motivation to combine references but instead relies on an improper "obvious to try" rationale:

The admonition that 'obvious to try' is not the standard under § 103 has been directed mainly at two kinds of error. In some cases, what would have been 'obvious to try' would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. ... *In others, what was 'obvious to try' was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.*

*See* MPEP § 2145(X)(B) (emphasis added). In this case, the Examiner's rationale is simply that Nasir and Pestka make it "obvious to try" the fluorescence technique -- a technique that Nasir states has "great potential" in the mycotoxin area -- to test for DON or other trichothecenes, i.e., some of the specific mycotoxins discussed in Pestka in relation to other assay techniques.

However, neither Nasir nor Pestka gives anything more than general guidance for how to achieve such a fluorescence polarization assay. For example, neither Nasir nor Pestka teach what fluorophore to use or what antibody to use in a fluorescence polarization assay for DON and other trichothecenes. Thus, the Examiner has not identified any proper suggestion or motivation to combine the teachings of the Nasir and Pestka references.

With respect to elements (2) and (3), claims 1, 5, and 10 recite that the tracer is able to bind to antibodies "to produce a detectable change in fluorescence polarization." In particular, the Examiner has failed to identify any prior art teaching of a tracer, comprising DON or other trichothecene conjugated to a fluorophore, that has this special property. The Examiner has not identified any teaching that a DON or other trichothecene conjugated to a fluorophore would be able to bind to an antibody. Nor has the Examiner identified any teaching that any binding would produce a detectable change in fluorescence polarization. In this regard, Nasir teaches that even if binding between tracer and antibody occurs little polarization shift may be observed, due to a phenomenon called the "propeller effect." See Nasir, p. 180. Moreover, the Pestka reference does not refer to fluorescence polarization at all, and the Nasir reference does not refer to DON or trichothecenes specifically. As a result, the Examiner has failed to identify a prior art teaching of a tracer, comprising DON or other trichothecene conjugated to a fluorophore, that has the property of being able to bind to an antibody to produce a detectable change in fluorescence polarization.

Accordingly, Applicants submit that claims 1, 5, and 10 are allowable over the prior art of record, including Nasir and Pestka. Applicants further submit that claims 2-4, 6-9 and 11 are also allowable as depending from allowable claims.

## **II. Information Disclosure Statement**

The Examiner has alleged that Applicants' Information Disclosure Statement does not fully comply with 37 C.F.R. § 1.98 because Applicants did not provide a translation of the complete German patent document no. 4,013,004. In fact, 37 C.F.R. § 1.98 does not require such a translation, and the Examiner is required to consider a non-English reference even when a complete translation is not provided:

If no translation is submitted, the examiner will consider the information in view of the concise explanation and insofar as it is understood on its face, e.g., drawings, chemical formulas, English abstracts, in the same manner that non-English language information in Office search files is considered by examiners in conducting searches.

See MPEP § 609(III)(A)(2). Instead of a complete translation, 37 C.F.R. § 1.98 requires Applicants to provide a "concise explanation of the relevance" of each non-English reference listed in the Information Disclosure Statement. Applicants complied with this requirement by submitting an English language abstract of the German patent document as the concise explanation of its relevance. See MPEP § 609(III)(A)(3) ("Submission of an English language abstract of a reference may fulfill the requirement for a concise explanation."). Accordingly, Applicants respectfully request the Examiner to consider the German patent document listed in the Information Disclosure Statement and to indicate such consideration.

### CONCLUSION

Applicants submit that the present application is now in condition for allowance and notice to that effect is hereby requested. Should the Examiner feel that further dialog would advance the subject application to issuance, the Examiner is invited to telephone the undersigned at any time at (312) 913-0001.

Respectfully submitted,  
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